Operating Instructions
Validation Tool Kit, ASTM
For use with USP Apparatus #1 & #2

P/N VALTOL-ASTM
Revision 2.0
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Revision History

Rev.	Description	Revised By	Revised On	Approved By	Approved On
A	Initial Release	RM	6/15/10	RM	6/15/10
2.0	Formatting	DM	10/8/14	RM	10/8/14

1.0 General Information

1.1 Introduction

Thank you for purchasing the QLA Validation Tool Kit, ASTM. This kit contains a variety of unique measuring tools and gages that provide an accurate reading of vessel plate levelness, paddle or basket shaft wobble, basket wobble, paddle or basket shaft verticality, paddle or basket height, vessel centering and vessel verticality as described in the new FDA specifications outlining the use of an Enhanced Mechanical Calibration procedure as an alternate approach to current Apparatus Suitability procedure for Dissolution Apparatus 1 and 2 as described in the USP General Chapter <711> Dissolution. The ASTM kit is maintenance free, easy to use and should be returned to QLA once a year for recalibration.

1.2 Product Specifications

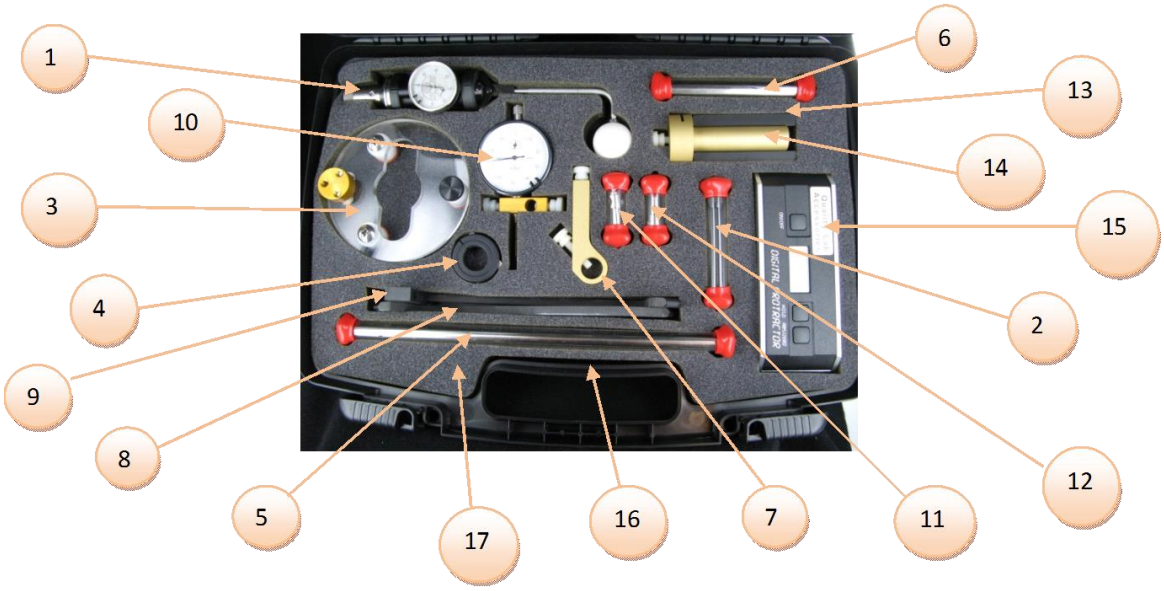
See individual Certificates of Calibration and Traceability.

2.0 Unpacking

The plastic storage box has been designed to minimize any damage that may occur during transport and can also be used to ship the ASTM Kit back to QLA for recalibration. Check the shipping container for any damage during transport. Unpack the individual parts carefully. After unpacking, check the parts for possible damage. Report any damage to the forwarding shipper immediately and inform QLA or your local representative.

3.0 Product Description

3.1 Diagram of Validation Tool Kit, ASTM



Item #	Description	Part Number
1	Vessel Centering and Verticality Alignment Gage	970-05-21
2	Anti-Rotation Handle	Included with Gage
3	Wobble Bracket Assembly	970-05-23
4	Shaft Collar	COLLAR-75
5	Indicator Shaft (Long)	10001006
6	Indicator Shaft (Short)	10001015
7	Indicator Bracket Assembly	97-05-25
8	Go, No-Go Gage	GNGDEP
9	Depth Set Gage	DEPSET-25
10	Dial Indicator Assembly	970-05-24
11	Spin Shaft Adapter for Hanson	ADPT-HR
12	Spin Shaft Adapter for VanKel / Varian	ADPT-VK
13	80mm Standard	STD80
14	80mm Spacer	SPCR80
15	Digital Verticality Meter	VERTMET-MI
16	Plastic Storage Case	6785TC
17	Foam Insert	Current Version

4.0 Installation / Operating Instructions

4.1 Digital Verticality Meter, Part Number VERTMET-MI

4.1.1 Diagram, Front of Digital Verticality Meter

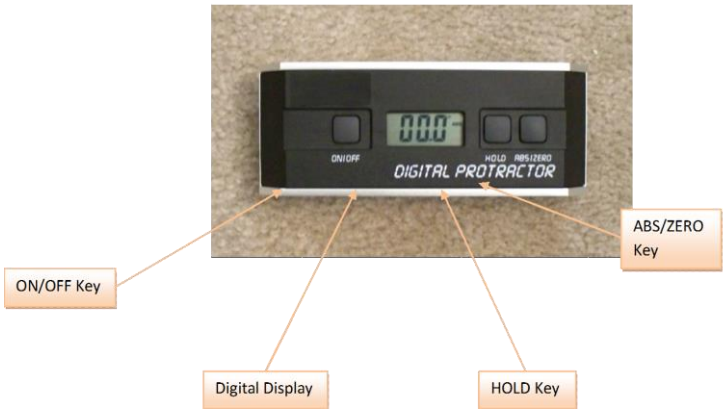


Figure 1

4.1.2 Diagram, Back of Digital Verticality Meter

Figure 2

4.1.3 Key function, ON/OFF

This key is used to turn the meter on or off and to enable the recalibration mode. See Section 4.1.7 of this manual for recalibration instructions.

4.1.4 Key Function, ABS/ZERO

This key is used to turn the meter on or off and to enable the recalibration mode. See Section 4.1.8 of this manual for recalibration instructions.

4.1.5 Key Function, HOLD

This key is used to hold the value on the digital display while measuring an angle. Place the meter against the paddle or basket shaft as shown in Figure 3. Wait six seconds and then press the “HOLD” key. While still holding the meter in position, the “Hold” Icon located on the digital display will begin blinking for about six seconds and then become solid. Once the icon becomes solid, the meter can be removed from the shaft and the value shown on the display will remain. To disengage the hold function, press the HOLD key again.

4.1.6 Battery Life Indicator

The Digital Verticality Meter is powered by a 3 Volt Lithium Battery, type CR2032. A new battery should provide about 500 hours of use. If the battery is low, the battery icon will be illuminated on the digital display. Replace with a new battery immediately.

4.1.7 Calibration, Accuracy Test

Perform this three step test before using this meter. Also perform this test any time the meter has been dropped or is used in an environment that varies more than 5 Degrees C from the environment in which it was last recalibrated.

STEP #1: Turn the meter on and press the ABS / Zero key until the “ABS” Icon appears in the digital display.

STEP #2: Position the meter with the display facing you on a clean, flat horizontal surface as shown in Figure 3. (The test surface does not have to be perfectly level) Wait ten seconds until the reading has completely settled and note the angle on the display.

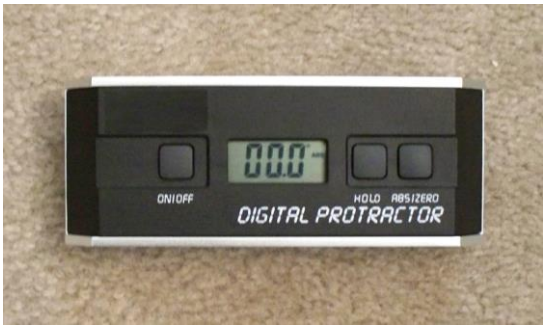


Figure 3

Step #3: Rotate the meter end-to-end so the display is facing away from you as shown in Figure 4. Make sure to position the meter in exactly the same spot and wait ten seconds before noting the reading on the display.

Figure 4

NOTE: If any two readings vary from one another by more than 0.1 degree, the meter MUST be recalibrated.

4.1.8 Calibration, Recalibrating Instructions

Follow these five easy steps to recalibrate the meter thru out its entire 360 degree range by electronically calibrating two horizontal angles.

STEP #1: With the meter turned on, press and hold the ON / OFF key for six seconds or until the display goes blank.

STEP #2: Press the ON / OFF key again to enable the recalibration mode and position the meter on a flat surface with the lettering on the front, right side up as shown in Figure 5. The number -1- will appear on the display.

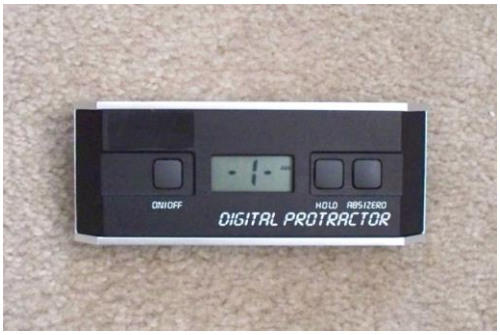


Figure 5

STEP #3: Press the ABS / ZERO key and the -1- will begin blinking for about four seconds and then change to -2- as shown in Figure 6.

Figure 6

STEP #4: Rotate the meter 180 Degrees horizontally so it faces away from you with the lettering right side up as shown in Figure 7.

HOLD– Push to "freeze" displayed angle in Horizontal or Relative mode which can be set by ABS/ZERO button (ABS or HOLD will be shown on LCD), please note that the unit should be in position for 6 seconds when "HOLD" flash. Push again to release.
ABS/ZERO– Push to set measuring mode between horizontal mode and relative measuring mode. Will not work in HOLD.
ON/OFF– Push ON/OFF shortly and the unit will work in measuring mode and display the angle. When press this button and hold for 6 seconds, it will be turn off and need to recalibrate when turn it on again.
See User Manual for Recalibrating Instruction.

Figure 7

STEP #5: Press the ABS / ZERO key and the -2- will begin blinking for about four seconds and then display a reading. The recalibration is now complete.

4.2 Checking Vessel Plate Levelness

4.2.1 The vessel plate levelness can be checked using the Digital Verticality Meter, Part Number VERTMET-MI.

Important: An Accuracy Test and/or Recalibration Of The Digital Verticality Meter Must Be Performed Before Use To Ensure Accurate Readings! See Section 4.1.7 of this manual for accuracy test and recalibration instructions.

4.2.2 Place the Digital Verticality Meter at the approximate center of the dissolution tester vessel plate and observe the reading.

4.2.3 The tester is considered adequately leveled when the reading is “0” Degrees, +/- 0.5 Degrees.

4.2.4 Adjustments to the tester can be made by raising or lowering the adjustable feet located on the base of the tester. (Please refer to the dissolution testers operation manual for their recommended procedure.)

4.3 Setting Paddle / Basket Height

4.3.1 The paddle or basket height can be set by placing the 25mm depth gage, (Part Number DEPSET-25) onto the paddle or rotating basket assembly by holding the support arm onto the drive shaft and making sure the top of the gage is touching the bottom of the paddle blade or rotating basket as shown in Figure 8.

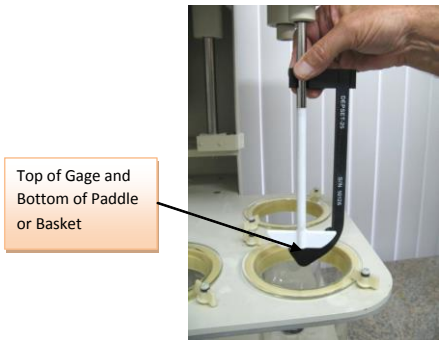


Figure 8

4.3.2 The paddle or basket assembly is lowered until the bottom of gage touches the inside bottom of the vessel as shown in Figure 9.

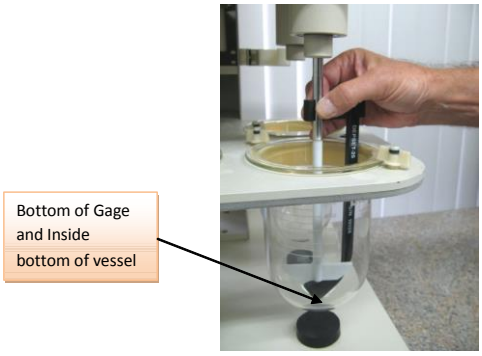


Figure 9

4.4 Checking Paddle / Basket Height

4.4.1 After setting the paddle or basket height. The height can be checked by using the Go / No-Go Gage as outlined below.

4.4.2 With the dissolution drive head lowered to its normal operating position, the smaller knob labeled “GO” must fit in between the bottom of the paddle or rotating basket and the bottom of the vessel. While the larger knob labeled “NO-GO” must not.

4.4.3 If the “GO” knob does not fit or the “NO-GO” knob does, the height needs to be adjusted. (See Sections 4.2.1 -4.2.3)

4.5 Measuring Paddle Wobble

4.5.1 For Hanson and Distek Tester

4.5.1.1 The paddle wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure 10.

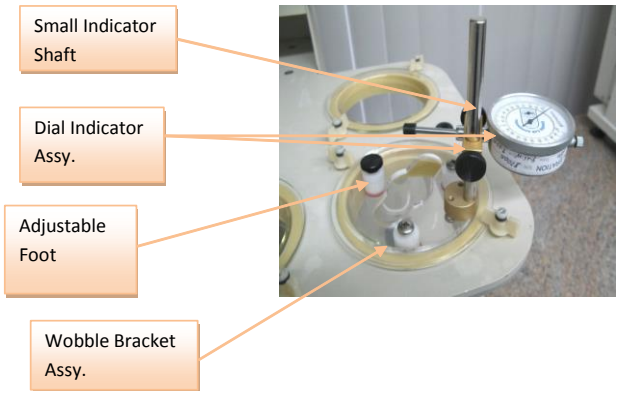


Figure 10

4.5.1.2 Place the wobble meter onto the top of the dissolution vessel and move the adjustable foot in or out until the assembly is secured to the inside of the vessel as shown in Figure 10.

4.5.1.3 With the paddle shaft secured, lower and position the dissolution drive head so that the dial indicator probe is located about 2cm above the top of the paddle blade and adjust the location of the indicator assembly to establish a pre-load of at least one revolution of the indicator dial. Tighten the thumb screws to lock the gage in place. See Figure 11.

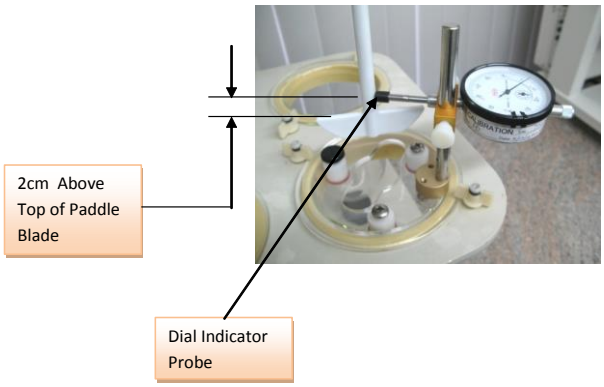


Figure 11

4.5.1.4 Set the dissolution tester to 25 RPMs. Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with “0” on the indicator. As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading (T.I.R.) or wobble. Each division on the dial indicator is equal to .01mm.

4.5.2 For VanKel / Varian Testers

4.5.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in Figure 12.

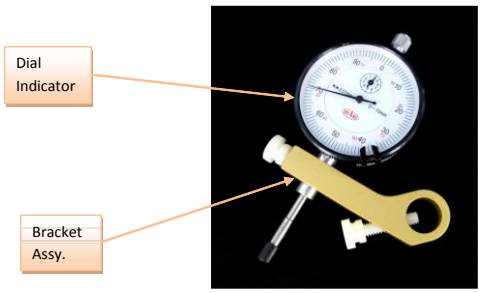


Figure 12

4.5.2.2 Place the indicator assembly onto the centering ring guide post as shown in Figure 13.

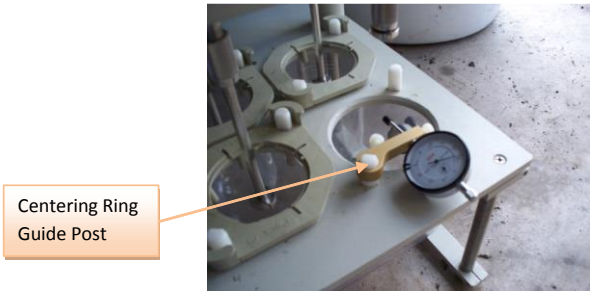


Figure 13

4.5.2.3 Repeat Sections 4.4.1.3 & 4.4.1.4

4.6 Measuring Basket Shaft Wobble

4.6.1 For Hanson and Distek Testers

4.6.1.1 The basket shaft wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure 10.

4.6.1.2 Place the wobble gage onto the top of the dissolution vessel and move the adjustable foot in or out until the assembly is secured to the inside of the vessel as shown in Figure 10.

4.6.1.3 With the basket shaft secured, lower and position the dissolution drive head so that the dial indicator probe is located about 2cm above the top of the shaft hub and adjust the location of the indicator assembly to establish a pre-load of at least one revolution of the indicator dial. Tighten the thumb screws to lock the gage in place. See Figure 14.

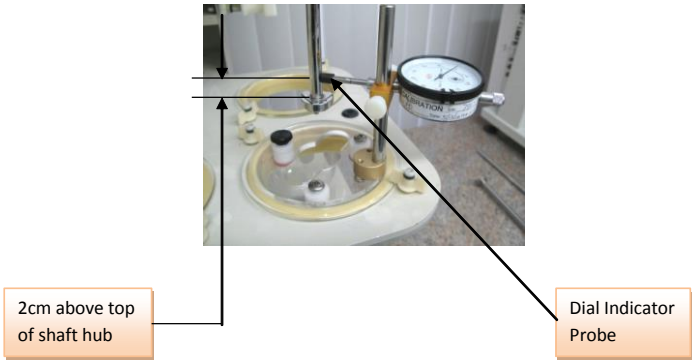


Figure 14

4.6.1.4 Set the dissolution tester to 25 RPMs. Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with “0” on the indicator. As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading (T.I.R.) or wobble. Each division on the dial indicator is equal to .01mm.

4.6.2 For VanKel / Varian Testers

4.6.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in Figure 12.

4.6.2.2 Place the indicator assembly onto the centering ring guide post as shown in Figure 13.

4.6.2.3 Repeat Sections 4.5.1.3 & 4.5.1.4

4.7 Measuring Basket Wobble

4.7.1 For Hanson and Distek Testers

4.7.1.1 The basket wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure 10.

4.7.1.2 Place the wobble gage onto the top of the dissolution vessel and move the adjustable foot in or out until the assembly is secured to the inside of the vessel as shown in Figure 10.

4.7.1.3 With the basket secured to the shaft, lower and position the dissolution drive head so that the dial indicator probe is touching the bottom rim of the basket and adjust the location of the indicator assembly to establish a pre-load of at least one

revolution of the indicator dial. Tighten the thumb screws to lock the gage in place. See Figure 15.

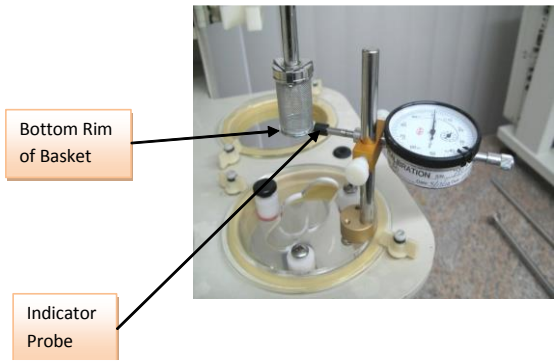


Figure 15

4.7.1.4 Set the dissolution tester to 25 RPMs. Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with “0” on the indicator. As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading (T.I.R.) or wobble. Each division on the dial indicator is equal to .01mm.

4.7.2 For VanKel / Varian Testers

4.7.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in Figure 12.

4.7.2.2 Place the indicator assembly onto the centering ring guide post as shown in Figure 13.

4.7.2.3 Repeat Sections 4.6.1.3 & 4.6.1.4

4.8 Measuring Paddle/ Basket Shaft Verticality

4.8.1 The Digital Verticality Meter (Part Number VERTMET-MI) is used to measure the paddle/basket shaft verticality.

Important: An Accuracy Test and/or Recalibration Of The Digital Verticality Meter Must Be Performed Before Use To Ensure Accurate Readings! See Section 6 of this manual for accuracy test and recalibration instructions.

4.8.2 Turn the meter on and press the ABS / ZERO key until the “ABS” icon appears on the digital display. Place the meter against the paddle or basket shaft as shown in Figure 16. The meter should be positioned with

the “V” grove against the shaft. Keep the meter motionless for six seconds and then record the value shown on the digital display. This value is the angular difference from True Horizontal.

4.8.3 To calculate the shaft verticality, use the example below:
Subtract the value shown on the meter (In Degrees) from 90 Degrees. This new value is the shaft verticality.

Example: If the value on the meter shows 89.7. *Then 90 Degrees Minus 89.7 Degrees, Equals 0.3 Degrees Shaft Verticality.*

The acceptable shaft verticality value is 90.0 +/- 0.5 Degrees.

Figure 16

NOTE: An arrow located on the left side of the digital display as shown in Figure 3, will indicate which direction to move the dissolution tester to achieve true verticality. The adjustable feet located on the base of the dissolution tester can be raised or lowered to accomplish this.

4.9 Measuring Vessel Centering

4.9.1 For Testers with One-Piece Shafts

4.9.1.1 Raise the dissolution tester to its highest position. Remove any existing paddle or basket shaft and replace it with the Indicator Shaft with Gage as shown in Figure 17.

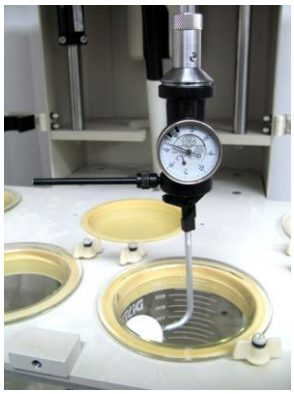


Figure 17

4.9.1.2 Insert the indicator shaft into the spindle such that the hole on the shaft protrudes about 1 inch below the spindle assembly.

4.9.1.3 Attach the top of the gage to the bottom of the indicator shaft by turning the knurled knob clockwise until snug. Use the anti-rotation handle to insert thru the indicator shaft. Hold the gage handle in place and then fully tighten the knurled knob. Raise the assembled gage into the spindle assembly and then fully tighten the Chuck Assembly. (Chuck assemblies are not used on Distek Dissolution Testers).

4.9.1.4 While gently pressing back on the gage shaft to avoid hitting the vessel rim or centering ring as shown in Figure 18. Lower the dissolution drive head so that the indicator ball is positioned about 2mm above the top of the vessels spherical radius. (This approximates the normal paddle or basket position.)

Figure 18

4.9.1.5 Set the dissolution tester speed to 25 RPMs and place one finger in front of the anti-rotation handle as shown in Figure 19. (Some Distek 5100 series instruments may be equipped with a drive

head position limit switch that prevents spindle rotation. These instruments require manual rotation.)

Figure 19

4.9.1.6 Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with 40 on the indicator.

4.9.1.7 As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading or T.I.R.. Each division on the dial indicator is equal to .05mm.

4.9.1.8 Stop the spindle rotation and raise the drive head so that the indicator ball is near the top of the vessel just below the rim and repeat Sections 4.7.1.5 to 4.7.1.7

4.9.2 For Testers with Two-Piece, Spin-Off Shafts

4.9.2.1 Follow the instructions in Section 4.7.1 with the following exceptions. Remove only the lower portion of the paddle or basket shaft assembly and replace it with one of the following Spin-Shaft adapters as shown in Figure 20. (Distek Testers do not require the use of an adapter.)

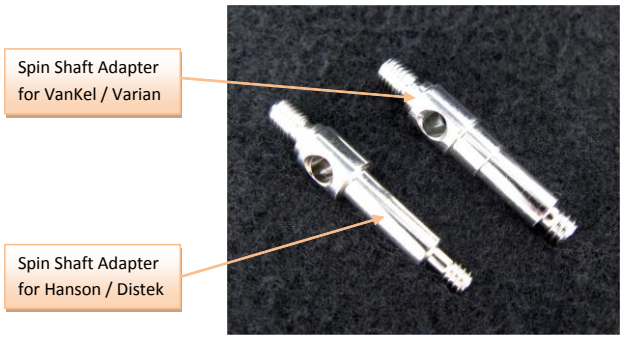


Figure 20

4.10 Calculating Vessel Centering

4.10.1 The actual vessel centering or spindle to vessel misalignment is calculated by dividing the total indicated reading or T.I.R. by two.

Example: The dial indicator moved clockwise from 40 to 15. The total indicated reading is 1.5mm. Thus, 1.5mm divided by two equals .75mm.

Example: The dial indicator moved clockwise from 40 to 25. The total indicated reading is 2.5mm. Thus, 2.5mm divided by two equals 1.25mm.

4.11 Measuring Vessel Verticality

4.11.1 For VanKel/Varian, Hanson or Distek testers, the centering gage is also used to measure the vessel verticality by following the steps below.

NOTE: The Anti-Rotation Handle may be removed to measure vessel verticality.

STEP #1: While gently pressing back on the gage shaft to avoid hitting the vessel rim or centering ring, lower the dissolution drive head so that the indicator ball is positioned about 2mm above the top of the vessels spherical radius as shown in Figure 21. (This approximates the normal paddle or basket position) Then install the Shaft Collar onto the left rear leg of the dissolution tester as shown in Figure 22.

NOTE: For VanKel / Varian Dissolution Testers, the Shaft Collar is not required. Use the adjustable stop located on the left rear leg to adjust the position of the drive head. See Figure 10.

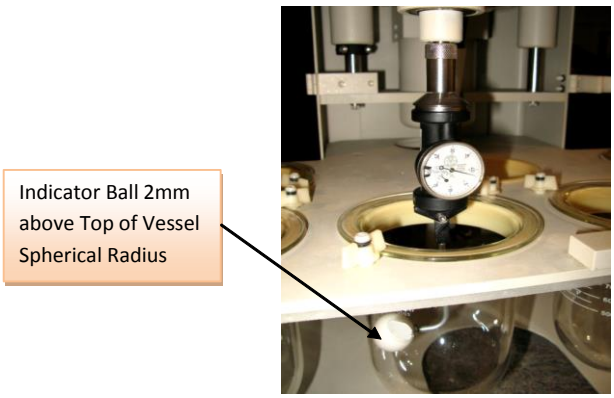


Figure 21

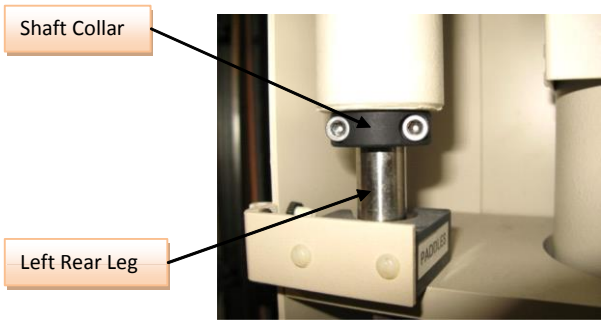


Figure 22

STEP #2: Rotate the dial face so that the pointer position coincides with 40 on the indicator.

STEP #3: While gently pressing back on the gage shaft, raise the dissolution drive head high enough to insert the appropriate 80mm Spacer or 80mm Standard as shown in Figures 23 and 24.

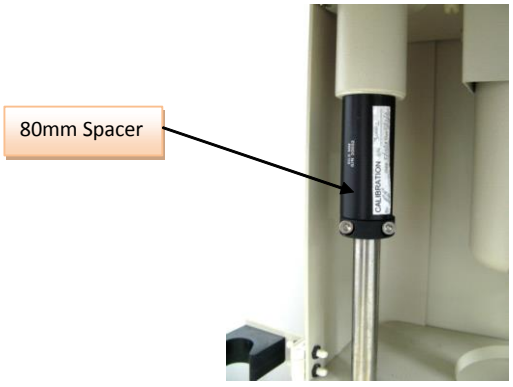


Figure 23

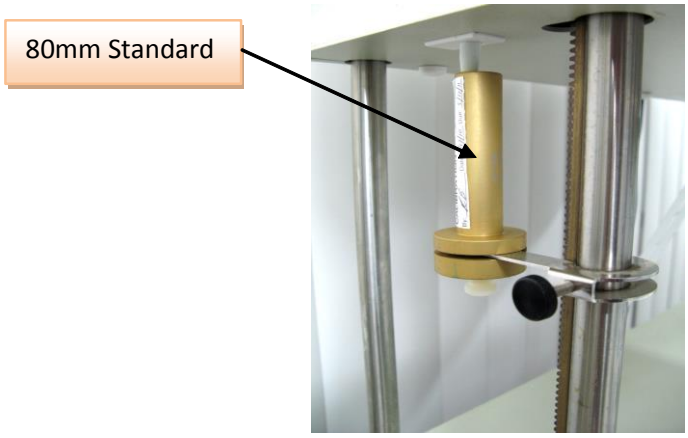


Figure 24

STEP #4: While gently pressing back on the gage shaft to avoid hitting the vessel rim or centering ring, lower the dissolution drive head until it touches the top of the standard or spacer, release the gage shaft and observe the reading on the gage. The difference between the reading at the bottom of the vessel and the top of the vessel is the displacement.

STEP #5: Rotate the gage 90 Degrees and then repeat steps 2 thru 4.

STEP #6: Repeat steps 2 thru 5 for each shaft location.

4.12 Calculating Vessel Verticality

A simple calculation has been performed to determine that the maximum allowable displacement over a distance of 80mm at a 1 Degree angle shall not exceed 1.36mm.

Example: The dial indicator moved clockwise from 40 to 5. The displacement or total indicated reading is .50mm. This vessel Passed.

Example: The dial indicator moved counter clockwise from 40 to 30. The displacement or total indicated reading is 1.00mm. This vessel Passed.

Example: The dial indicator moved counter clockwise from 40 to 5. The displacement or total indicated reading is 3.50mm. This vessel Failed.

5.0 Qualification and Validation

Prior to shipment, the kit is calibrated and includes a Certificate of Calibration and Traceability. The complete kit should be returned to QLA for recalibration once a year.

6.0 Maintenance

Although the measuring tools and gages contained in this kit are maintenance free and do not require any daily service, it is recommended that after each use, the gages and tools are returned to the plastic protective case for storage.

7.0 Warranty

This parts contained in this kit are warranted to be free from defects in materials and workmanship under normal installation, use and service for a period of (1) year from the date of purchase as shown on the purchase order receipt. The obligation of QLA under this warranty shall be limited to repair or replacement (at our option) during the warranty period, provided the product is returned to QLA with transportation charges prepaid. This warranty shall be invalid if the product is damaged as a result of defacement, misuse, accident, destruction or alteration of the serial numbers, repair alteration or maintenance by any person or party other than our own service facility or authorized QLA service technician.